considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and phone number and will need to refer to Announcement Number 314. You will receive a complete program description, information on application procedures and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Oppie Byrd, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., room 300, Atlanta, Georgia 30305, (404) 842–6548. Programmatic technical assistance may be obtained from John E. Parker, National Institute for Occupational Safety and Health, Division of Respiratory Disease Studies, 944 Chestnut Ridge Road, Mailstop 122, Morgantown, West Virginia 26505, (304) 291–4301.

Please refer to Announcement Number 314 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone: (202) 783–3238.

Dated: April 23, 1993.

Richard A. Lemen,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–10154 Filed 4–29–93; 8:45 am]

BILLING CODE 4160–19–P

Workshops on Community Epidemiologic Studies Near the Former Feed Materials Processing Center (FMPC) in Fernald, OH; Public Meetings

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), announces the following meetings.

Name: Workshops on Community Epidemiologic Studies Near the Former FMPC in Fernald, Ohio.

Date: May 19, 1993.

Time: 1 p.m.–5 p.m.

Place: Sheraton Springdale Hotel, 11911 Sheraton Lane, Cincinnati, Ohio 45246.

Date: May 19, 1993.

Time: 7:30 p.m.–10 p.m.

Place: Crosby Elementary School, 8382 New Haven Road, Harrison, Ohio 45030.

Date: May 20, 1993.

Time: 8 a.m.–12 noon.

Place: Sheraton Springdale Hotel, 1191 Sheraton Lane, Cincinnati Ohio 45246.

Status: Open to the public for observation and comment, limited only by space available. Seating space for 50 individuals will be available at each meeting.

Purpose: Under a Memorandum of Understanding with the Department of Energy (DOE), the Department of Health and Human Services has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. The FMPC located in Fernald, Ohio, operated under contract for DOE from 1951 until production was suspended in 1988. The plant produced uranium metal products for use as feed materials for reactors located at other DOE sites. During operations radioactive material migrated off the plant site. The goal of an analytic epidemiologic study would be to determine the potential health effects to community residents from exposure to radioactive material released to the environment from the plant.

Matters to be Discussed: An invited group of epidemiologists, statisticians, public health professionals, physicians, and members of the community will discuss steps for assessing appropriate analytic epidemiologic studies at the former FMPC. The discussions will focus on evaluation of various study designs, determination of methods for power calculations, utilization of dose estimates, and involvement of the community in the study process. Invited participants will provide CDC with their individual advice and comments. Information provided by the participants will be used by CDC in planning the epidemiologic research projects for the community near the former FMPC.

At the conclusion of the meetings, all attendees will have an opportunity to provide oral and/or written comments for the record.

For a period of 15 days following the meetings, through June 4, 1993, the official record of the meetings will remain open in order that additional material or comments may be submitted to be made part of the record of the meetings.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Kathy George, M.P.H., Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE., (F–35), Atlanta, Georgia, 30341–3724, telephone 404/488–7060.

Dated: April 26, 1993.

Elvin Hilyer,

Associated Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–10152 Filed 4–29–93; 8:45 am]

BILLING CODE 4160–18–M

CDC Advisory Committee on the Prevention of HIV Infection; change of meeting dates

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 58 FR 19823—dated April 16, 1993.

SUMMARY: Notice is given that the meeting for the CDC ACPHI Subcommittee on Preventing Risk Behaviors Among School Students has been rescheduled. The meeting times, location, and purpose announced in the original notice remain unchanged.

ORIGINAL TIME AND DATES: 8:30 a.m.–5 p.m., May 3–4, 1993.

NEW DATES: June 13–14, 1993.

FOR MORE INFORMATION CONTACT: Connie Granoff, Committee Assistant, Office of the Associate Director for HIV/AIDS, CDC, 1600 Clifton Road, NE, Mailstop E–40, Atlanta, Georgia 30333, telephone 404/639–2918.

DATED: April 27, 1993.

Robert L. Foster,

Assistant Director, Office of Program Support Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–10294 Filed 4–29–93; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 93E–0067]

Determination of Regulatory Review Period for Purposes of Patent Extension; AMBIEN®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AMBIEN® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Karin L. Bolte, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product AMBIEN®. AMBIEN® (zolpidem tartrate) is indicated for the short-term treatment of insomnia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AMBIEN® (U.S. Patent No. 4,382,938) from Synthelabo, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated March 11, 1993, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of AMBIEN® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for AMBIEN® is 2,713 days. Of this time, 1,296 days occurred during the testing phase of the regulatory review period, while 1,417 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: July 15, 1985. The applicant claims November 15, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND was placed on clinical hold on December 10, 1984, and was removed from clinical hold on July 15, 1985. Therefore, the IND effective date is July 15, 1985.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: January 30, 1989. The applicant claims January 26, 1989, as the date the new drug application (NDA) for AMBIEN® (NDA 19–908) was initially submitted. However, FDA records indicate that NDA 19–908 was initially submitted on January 30, 1989.

3. *The date the application was approved*: December 16, 1992. FDA has verified the applicant's claim that NDA 19–908 was approved on December 16, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 29, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 27, 1993, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–10173 Filed 4–29–93; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration Advisory Council

Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory bodies scheduled to meet during the month of June 1993.

Name: Advisory Commission on Childhood Vaccines.

Date and Time: June 7, 1993, 9 a.m.–5 p.m.; June 8, 1993, 8:30 a.m.–12 p.m.

Place: Conference Rooms G&H, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

The meeting is open to the public.

Purpose: The Commission: (1) advises the Secretary on the implementation of the Program, (2) on its own initiative or as the result of the filing of a petition, recommends changes in the Vaccine Injury Table, (3) advises the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions, (4) surveys Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b), and advises the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and (5) recommends to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the National Vaccine Injury Compensation Program.

Agenda: The first day of the meeting will consist of simultaneous meetings of the Commission's Working Subcommittees. The full commission will meet commencing at 9 a.m. until 2:45 p.m. and from 8:30 a.m. to 12 p.m. on Tuesday, June 8. Agenda items will include, but not be limited to, routine Program reports, reports from the National Vaccine Program and the National Vaccine Advisory Committee (NVAC), reports from the ACCV Subcommittees.

Name: Scientific Review Subcommittee of the Advisory Commission on Childhood Vaccines.

Date and Time: June 7, 1993, 3 p.m.–5 p.m.